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Trinity Biotech Announces FDA Approval of Premier Hb9210

DUBLIN, Ireland (December 6, 2011)…. Trinity Biotech plc (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced that it has obtained FDA approval for the Premier Hb9210.

The Premier instrument is a fully automated system that measures HbA1c in high and low throughput clinical laboratories. HbA1c, also known as glycated hemoglobin, is a measure of a patient's average blood sugar control over the last two to three months and is a key tool in the diagnosis and monitoring of diabetes. The current worldwide prevalence of diabetes is estimated to be 250 million and it is expected to reach 380 million people by 2025. Within the USA it is estimated that 12.9% of persons over the age of 20 have diabetes, 40% of whom are undiagnosed. The worldwide costs of diabetes in 2007 were approximately $232 billion and this is expected to increase to $302 billion by 2025.

FDA approval enables the instrument to be launched and sold in the United States and will greatly facilitate sales in other international jurisdictions. The instrument has already been CE marked for sale in Europe and was formally launched in Quarter 2, 2011.

In the USA, Trinity will market and sell the Premier through a combination of direct selling through our existing US salesforce and through Fisher Healthcare's extensive distribution network. Fisher Healthcare is one of the leading distributors of HbA1c products in the USA with an installed base of approximately 1,000 A1c instruments. Fisher has recently signed a distribution agreement with Trinity and will be exclusively selling the Premier instrument in the USA.

Trinity also recently announced an agreement to exclusively supply Menarini Diagnostics with the new Premier instrument for distribution in European territories. As one of Europe's leading pharmaceutical and diagnostics companies, Menarini, with a turnover of €2.6 billion and 12,000 employees, is the market leader in HbA1c measurement in Europe. Menarini has a market share of 40% in the European HbA1c market, a large installed base of equipment and over 20 years experience in HbA1c measurement.

We are also making significant progress in obtaining the necessary approvals in other key markets. In June we submitted our application to the Chinese regulatory authorities and we expect to receive approval by the end of 2012. This will represent an excellent opportunity to build on our existing installed base in China.

The Premier analyser is a best in class instrument with the following key advantages :

- Results available in 1 minute, making it the fastest test in the market;
- State of the art software using touchscreen technology to facilitate ease of use for operators;
- Patented exclusive boronate affinity technology, therefore eliminating interference from hemoglobin variants;
- Modular instrument which will significantly reduce the cost of on-site maintenance.

Commenting on the announcement, Trinity Biotech's CEO, Mr Ronan O'Caoimh said, "HbA1c testing is already a US$300 million global market with enormous growth potential. We have now the fastest, most user friendly and state of the art HbA1c analyser in the world. FDA approval of the instrument, in conjunction with its recent CE marking, now gives us access to the US and European markets, the two most important individual markets in the world, and will accelerate the approval process in other key markets such as Brazil and China. Together with our partners, Menarini in Europe and Fisher in the USA, we are ideally positioned to become a significant and serious player in the global HbA1c market in the coming years."

Forward-looking statements in this release are made pursuant to the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.

Trinity Biotech develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States, Germany, France and the U.K. and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information please see the Company's website: www.trinitybiotech.com.